

### **REMARKS**

Currently, claims 60, 64-65, 67-72, 74, and 76-83, including independent claim 60, are pending in the present application. As indicated above, independent claim 60 has been amended to include the limitations of dependent claims 63, 66, and 73. As amended, independent claim 60 is directed to a kit for detecting *Helicobacter pylori*. The kit comprises a breath testing device that contains a substrate on which a visual indicating agent is disposed that is color sensitive to ammonia at a concentration of about 20 to about 500 parts per million. The substrate is located within a passage of a tubular carrier portion of a breath collecting device. The visual indicating agent contains Michler's hydrol.

In the Office Action, independent claim 60 was rejected under 35 U.S.C. § 103(a) as being obvious over the English abstract of JP62151757 ("JP '757") in view of U.S. Patent No. 5,174,959 to Kundu, et al. JP '757 describes the use of 4,4'-bisdimethylamino diphenyl carbinol for detecting volatile sulphides (e.g., mercaptan) in the mouth. A sulfonate compound (e.g., sodium anthraquinone disulfonate, sodium benzenesulfonamide, or sodium sulfimide benzoate) is also employed to increase detection sensitivity. As an initial matter, Applicants note that JP '757 is directed to the detection of **volatile sulphides** – not ammonia. In any event, JP '757 fails to disclose various aspects of independent claim 60. For example, independent claim 60 requires that the visual indicating agent is color sensitive to ammonia at a concentration of about 20 to about 500 parts per million (previously dependent claim 63) and that the substrate on which the visual indicating is disposed is located within a passage of a tubular carrier

portion (previously dependent claim 73). As correctly recognized by the Examiner, JP '757 fails to disclose or suggest these limitations.<sup>1</sup>

Independent claim 60 was also rejected in the Office Action under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,432,094 to Delente in view of U.S. Patent Application Publication No. 2002/0068364 to Arai, et al. and U.S. Patent No. 4,407,960 to Tratnyek. Delente describes a detector that includes a material positioned in a chamber containing a breath sample. The material responds to the *moisture content of the breath sample* and determines from that parameter whether or not the sample is a true alveolar sample. For example, the material may include a moisture-sensitive indicator (e.g., cobalt chloride) impregnated into a paper.

As correctly noted by the Examiner, Delente fails to disclose the use of a visual indicating agent for ammonia that contains Michler's hydrol. Nevertheless, the Office Action indicated that it would have been obvious to use Michler's hydrol in the kit of Delente in light of the combined teachings of Arai, et al. and Tratnyek. Applicants respectfully disagree. The entire premise of Delente is based on detecting a change in "moisture" or humidity. There simply would have been no motivation whatsoever to remove the "moisture-sensitive" indicator of Delente and instead employ an indicator that produces a detectable change by gaseous ammonia. In fact, the teachings of the references provide no reasonable basis for expecting that the ammonia-sensitive dyes would function in the manner expressly required by Delente – i.e., as moisture detectors.

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<sup>1</sup> Sundu, et al. was also cited in combination with JP '757 for the teaching of a "kit." However, Sundu, et al. fails to cure the defects noted herein.

Finally, independent claim 60 was also rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Pub. No. 2004/0077093 to Pan in view of Arai, et al. and Tratnyek (referenced above). Pan is directed to method for detecting the presence of a bacteria in the gastrointestinal tract of a subject. The method comprises delivering a source of urea to the gastrointestinal tract of the subject, obtaining a fluid sample from the subject after the delivery of the urea source, contacting the fluid sample with a sensor, and optically detecting a color change in the sensor that is indicative of the presence of ammonia in the fluid sample. The sensor includes a dye having the capacity to become deprotonated and undergo a color change in the presence of ammonia. The contact conditions are controlled so that the sensor responds to the presence of ammonia in the fluid sample, but not to the pH of the fluid sample by undergoing an optically discernible color change. Suitable pH sensitive dyes are said to include bromophenol blue, bromothymol blue, methyl yellow, methyl orange, 2,4-dinitrophenol, 2,6-dinitrophenol, phenol red, and cresol red.

Nevertheless, as acknowledged by the Examiner, Pan fails to disclose one or more aspects of the claimed kit. For instance, Pan fails to disclose a visual indicating agent that contains Michler's hydrol as set forth in independent claim 60. The Office Action attempted to combine both Arai, et al. and Tratnyek with Pan to satisfy this limitation. Arai, et al. describes an integral multilayer analytical element that includes, among other things, an indicator layer having a dye precursor that changes in absorption wavelength as a result of the reaction with gaseous ammonia. Among a lengthy list of various dye precursors, Arai, et al. cursorily mentions the generic class of triarylmethane dye precursors. The Office Action uses this brief and generic reference

to triarylmethanes to look to Tratnyek for the disclose of Michler's hydrol as a triarylmethane dye. However, Tratnyek relates to a sterilization indicator for ethylene oxide and has nothing to do with ammonia detection. Further, in Tratnyek, the triarylmethane dye is actually reacted with an acidic compound to produce a color that changes to colorless in the presence of ethylene oxide. One of ordinary skill in the art would certainly not have been motivated to selectively pick and choose a single type of triarylmethane dye used in a reaction for detecting ethylene oxide for incorporation into the ammonia detection system of Pan.

Regardless, even if combined, the references still fail to disclose certain aspects of independent claim 60. The breath sampler of Pan, for example, includes a detection unit 105 that is separate and distinct from a breath handler 103 (See e.g., Figs. 1-2). The detection unit 105 includes an ammonia sensing membrane 127 attached to the bottom of a container 117, such as by ultrasonic or thermal welding. ¶ [0065]. In stark contrast, independent claim 60 requires that the substrate on which the visual indicating agent is disposed is *located within a passage of a tubular carrier portion*. In this manner, the substrate is able to more readily contact the breath sample when a user blows into the tubular carrier portion. Neither Arai, et al. nor Tratnyek cures this defect. Thus, for at least the reasons indicated above, it is respectfully submitted that independent claim 60 patentably defines over the cited references.

As a final note, claims 60-81 were rejected in the Office Action under the judicially created doctrine of obviousness-type double patenting in view of copending Application No. 10/687,270. Without commenting on the propriety of this rejection,

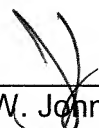
Applicants are nevertheless submitting herewith a terminal disclaimer to obviate this rejection.

Applicants respectfully submit that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Portner is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

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